

REMARKS

The March 31, 2004 interview with Examiners Odland and Bennett is appreciated.

With this proposed amendment the distinctions from the cited Swiggett patent (No. 4,485,817) are made clear. Even though the applicant does not believe Swiggett shows anything that would be considered a "handle" at the far end of the disclosed stapler tool, which is used by extending into a lumen of the body, the Examiners pointed out that the word "handle" in the claims should be read as broadly as possible, without any reference whatsoever to the specification or drawings. The undersigned does not fully agree that the specification cannot be consulted at all, but is nonetheless willing to amend the claims to point out the differences between the type of tool disclosed by Swiggett and the improvement which is the subject of the present invention.

As pointed out by the undersigned to the Examiners, the tool with which the invention is concerned is discussed in the disclosure and is generally as shown in the drawings, including the prior art drawings of Figures 1-4. This type of clip applying device has a handle or body 16 and a narrow, elongated stem 14 that carries staples that are applied by a tip 12 of the stem 14. The gripping handle 16 is elongated, and the stem 14 is elongated and much narrower than the handle. The stem 14 projects rigidly from the handle portion 16, and the fact of this

rigid projection is the very underpinning of the discussion in the specification regarding small movements or jerks of the hand holding the prior art device while applying pressure to the thumb/finger wings 18 to dispense a clip, as causing a seriously disruptive movement of the clip-applying tip 12 at a wound site or on a small blood vessel, tending to cause failure of the procedure.

The claims and the specification are now amended to describe the gripping handle as elongated, and the clip dispensing stem as elongated, much narrower than the handle and rigidly extending and projecting from the forward end of the handle. These words are not used in the original text, but the features are clearly shown in the drawings and in fact are disclosed through the disclosure of an off-the-shelf example, the VCS Clip Applier, referenced at page 8 of the specification.

These features, now added to claims 1 and 3, make manifest the distinction of the invention from Swiggett. Swiggett shows an entirely different type of clip applying tool, one which is intended to enter a small channel or lumen of the human body to apply a clip. The end portion or applicator 16 of Swiggett, which enters the body, is not intended to be a handle, and there is no disagreement on that point (it cannot be a handle if used as suggested by Swiggett). The Examiners suggest that it could be considered as a handle, and in response the claims now state that

the handle of the applicant's invention is an elongated gripping handle (which Swiggett's item 16 is not), with an elongated clip dispensing stem, much narrower than the handle, rigidly projecting forward from a forward end of the handle (also absent from Swiggett). Thus, even if one could hold the applicator end 16 of Swiggett with one hand while manipulating the actual handle or actuator 12 of Swiggett to eject a staple, this does not meet the limitations of claim 1 and 3.

The Examiner's rejection was based on obviousness. Swiggett does not teach or suggest anything toward the present invention because Swiggett has a flexible device for a different purpose than the applicant: Swiggett's device is flexible between the hand-held actuator 12 and the applicator end 16 for the purpose of allowing the applicator end to enter channels or lumens within the human body, extending around curves and turns. Swiggett's device is not intended to, nor does the patent teach it does, eliminate movement of the actuator tip at the instant of staple application by assuring that the hand which holds the applicator device does not also apply the force which dispenses a clip or staple. Swiggett teaches using his tool a different way. The applicant's claims now make clear that what is claimed is the modification of a conventional clip applier which has an elongated gripping handle with a narrow, elongated stem at its forward end from which clips are dispensed. Such a conventional

tool is difficult to use in situations of very small vessels, as explained in the specification, because the small but inevitable movement of the handle which is caused when the surgeon squeezes the thumb/finger actuators is magnified by the elongated clip stem 14, so that a clip is likely to be misapplied. In other situations, even if the hand can be taken into a body cavity while holding the handle 16 of the conventional clip applier tool, there might not be sufficient room to squeeze the actuator wings of the conventional tool (it may have to be held from the back end of the handle), again needing a solution. The invention is to fit a flexible force-applying cable or hydraulic or other device to the back end of the handle so that the actual clip actuation can be done by a foot pedal, by another person, or at least by another hand of the surgeon, a different one from the hand that holds the handle of the tool itself.

The Examiners seemed satisfied in the interview that any distinction made from the literal structure shown in Swiggett would support allowance of the apparatus claims. That distinction is now clearly presented.

Independent claim 9 is a method claim. The claim is believed clearly distinguishable from anything in the prior art, including Swiggett, because it requires the step of effecting dispensing and application of a clip at the site to be closed by engaging the remote actuator at the remote end of the flexible

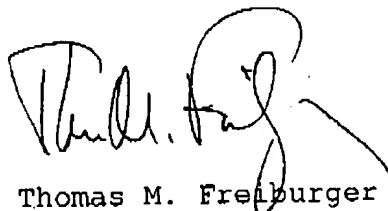
device, with the engaging of the actuator not being performed by the hand holding the handle of the clip applier. Even if the Examiner would take the position that Swiggett could be capable of such use, claim 9 is a method claim and Swiggett does not teach or in any way suggest or indicate the possibility of such use. An unobvious method of using even a well-known prior tool is patentable.

Claim 9 is amended to cite in the penultimate paragraph to more positively recite the step of gripping the handle in one hand and manipulating the handle so as to position the tip of the clip applier in the appropriate position.

This is submitted as a proposed amendment, for purpose of a brief further discussion with the examiner.

The Examiners' review of this proposed amendment will be appreciated, and it is asked that the Examiner then telephone the undersigned attorney.

Respectfully submitted,



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